

December 13, 2011

Ben Steffen, Acting Executive Director  
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Maryland Health Care Commission  
4160 Patterson Avenue  
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Re: Informal Written Comments on the Summary Report of Technical  
Advisory Group (TAG) on Oversight of Percutaneous Coronary Intervention  
Services

Acting Director Steffen and Commission Staff:

Anne Arundel Medical Center ("AAMC") submits these Informal Written Comments on the Summary Report of the Technical Advisory Group (TAG) on Oversight of Percutaneous Coronary Intervention (PCI) Services. AAMC currently offers both primary and non-primary PCI services to its community under waivers granted by the MHCC from the requirement in the current State Health Plan that PCI services can only be offered in hospitals with on-site open heart surgery capability. We understand that the MHCC must respond to the General Assembly in accordance with § 2-1246 of the State Government Article as required by Chapter 616, Laws of 2011, which Act requires that the MHCC develop recommendations for statutory changes needed to provide appropriate oversight of PCI services in Maryland and deliver a report and recommendations to the Governor by December 31, 2011. The TAG was created to assist in meeting the requirements of Ch. 616, and met four times and submitted a Summary Report released on December 8, 2011 on which comments were solicited. Informal comments must be submitted by 4 pm on December 13 to be considered at the MHCC meeting to be held on December 15, 2011. Due to the time constraints, AAMC reserves its right to submit additional comments at a later time.

AAMC must congratulate the members of the TAG and the MHCC Staff for their efforts in preparing the TAG report on such an important subject in a constrained time frame. AAMC in general supports the TAG Recommendations, and endorses the four "Recommendations Related to Statutory Changes" in the Report, summarized below, with one important exception:

1. MHCC statute should provide authority for oversight of PCI services which should apply at all hospitals providing PCI, with and without on-site cardiac surgery;

2. All programs providing PCI services should be required by law to undergo continuing evaluation of performance based on established and uniform standards, with renewal of authority to provide PCI Services being based on compliance with such standards;
3. MHCC should be added to the list of State agencies that can share information with respect to investigating quality or utilization review
4. The term “open heart surgery” in the statute should be changed to “cardiac surgery”.

AAMC recognizes that the MHCC has experience in reviewing PCI under the waivers that have been granted, and there is considerable benefit in continuing to use that experience. The concept that PCI services should be reviewed wherever they are provided also makes sense, in light of the recent negative publicity that has surrounded PCI activities at two hospitals in the State, both of which have on-site open heart surgery programs. Uniformly applied, clinically based standards designed to enhance quality are always highly desirable, and are heartily endorsed.

However, the consensus recommendations indicate that TAG does not feel that the certificate of need (CON) process is appropriate or useful for a review of the ability of any hospital to continue to offer PCI Services. AAMC wholeheartedly agrees.

The pPCI and npPCI programs, were approved through a waiver process and have been operating successfully without ever having undergone full CON review. The waiver, and the expedited process that was finally adopted for the waiver process, allow us to provide these valuable services to our community. Some version of the waiver program, focused on quality and periodic review, is the only practical alternative to keep these valuable and indeed life saving services available to communities such as ours. While in the past we have espoused the benefits of licensure, we think the process to be followed is more important than which agency is responsible for its administration, and support consolidating the review and oversight before the MHCC.

However, if a CON process for PCI services is to be adopted; the existing providers should be grandfathered. We will, of course, welcome any clinically approved quality indicators, including those that are related to volumes, but firmly believe that programs such as ours, which have been in existence for years, should not be subjected to CON review. We strongly support the views of those TAG members who expressed the view that “the only standards applied in oversight should be quality and volume (in the context of quality)”.

We also support the four recommendations of the TAG that are identified as “Can be implemented without statutory changes.” With respect to the issue of peer review, however, AAMC firmly believes that the MHCC should not mandate any specific peer review practices, most especially a mandated external peer review process. Hospitals are required to conduct peer

review and quality review processes for all services provided at the hospital, and hospitals should be free to craft a peer review for PCI services that is appropriate for the hospital.

The benefits of the waived PCI services at AAMC are many. The CON process cannot be permitted to destroy that benefit.

Respectfully submitted,



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President and Chief Executive Officer

cc: Delores Sands  
Paul Parker  
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Vanessa Aburn